

REMARKS

The Office Action mailed October 28, 2004, has been received and reviewed. Claims 10, 11, 15-18, 21-23, 27, 29-32, 34-38, 46 and 47 are currently pending and stand rejected. Claims 10, 11, 15, 16, 29 and 35 have been amended, claim 34 has been canceled, and new claim 48 has been added as set forth herein. All amendments and cancellations are made without prejudice or disclaimer. Reconsideration is requested. With the amendment of the claims as provided herein, and further in view of the arguments made hereinafter, the applicants contend that claims 10, 11, 15-18, 21-23, 27, 29-32, 35-38 and 46-48 are in condition for allowance and the same is respectfully requested.

Supplemental Information Disclosure Statement

Please note that a Supplemental Information Disclosure Statement was filed on November 14, 2003, and that no copies of the PTO/SB/08A were returned with the outstanding Office Action. Applicants respectfully request that the information cited on the PTO/SB/08A be made of record herein. It is respectfully requested that initialed copies of the PTO/SB/08A evidencing consideration of the cited references be returned to the undersigned attorney.

Rejection of Claims 10, 11, 15-18, 21-23, 27, 29-32, 34-38, 46 and 47 Under 35 U.S.C. § 112

Claims 10, 11, 15-18, 21-23, 27, 29-32, 34-38, 46 and 47 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants respectfully traverse this rejection, as hereinafter set forth.

Specifically, it was argued that claims 10, 11, 15, 16, 29 and 35 were of improper Markush form under 35 USC § 112 and that it was ambiguous if the vehicle contains three components or the vehicle contains one of the elements of the Markush group. Although applicants do not agree that any of the claims are indefinite, to expedite prosecution, the Markush language has been removed from each of independent claims 10, 11, 15, 16, 29 and 35.

Claims 15 and 16 were further thought to be unclear for reciting the phrases "two components" and "three components." These phrases have been removed from claims 15 and 16.

It was also thought that since claim 34 depended from claim 35, that it was indefinite. Although applicants do not agree with the rejection, to expedite prosecution, claim 34 has been canceled and new claim 48 depending from claim 35 has been added. Claim 48 includes the same language as canceled claim 34.

Lastly, the Office Action asserted that the viscosity of the vehicle is not accorded patentable weight to the vehicle because the generic claims are broad vehicle claims that contain polyvinylpyrrolidone, polysorbate or glycerol monolaurate, or lauryl lactate, and the vehicle that comprises the recited component would inherently possess that viscosity. (*See, Office Action*, page 3). However, applicants disagree with this rejection since the viscosity of a substance is a physical characteristic or property of the substance and the viscosity may be modified, thus, according patentable weight.

Reconsideration and withdrawal of the indefiniteness rejections of claims 10, 11, 15-18, 21-23, 27, 29-32, 35-38, 46 and 47 are requested.

Anticipation Rejection of Claims 10, 11, 15-17, 21-23, 27, 46 and 47 Under 35 U.S.C. § 102(b)

Claims 10, 11, 15-17, 21-23, 27, 46 and 47 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Daher et al. (U.S. Patent No. 4,376,118) (*Office Action*, at page 3). Applicants respectfully traverse this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Anticipation cannot be established since Daher et al. does not disclose each and every element of any of claims 10, 11, 15-17, 21-23, 27, 46 and 47. For instance, each of amended, independent claims 10, 11, 15 and 16 includes an element directed towards a stable non-aqueous single-phase biocompatible viscous vehicle comprising, *inter alia*, a polymer comprising polyvinylpyrrolidone. However, polyvinylpyrrolidone is not included in the solution of the tetracycline antibiotic salt of Daher et al. In fact, Daher et al. does not disclose the use of polyvinylpyrrolidone. Daher et al. also does not disclose a viscosity of a vehicle having between

about 1,000 and 10,000,000 poise, as recited in amended claims 10 or 11. Thus, amended, independent claims 10, 11, 15 and 16 cannot be anticipated.

Dependent claims 17, 21-23, 27, 46 and 47 are not anticipated, at the very least, as depending from novel independent claim 15 or 16.

Reconsideration and withdrawal of the anticipation rejections of claims 10, 11, 15-17, 21-23, 27, 46 and 47 are requested.

Anticipation Rejection of Claims 10, 11, 15, 16, 46 and 47 Under 35 U.S.C. § 102(e)

Claims 10, 11, 15, 16, 46 and 47 stand rejected under 35 U.S.C. § 102(e) as assertedly being anticipated by Lyle (U.S. Patent No. 5,814,323) (Office Action, at page 4). Applicants respectfully traverse this rejection, as hereinafter set forth.

Lyle does not expressly or inherently disclose each and every element of any of claims 10, 11, 15, 16, 46 and 47 as required for anticipation. For instance, Lyle does not disclose the use of polyvinylpyrrolidone, glycerol monolaurate and lauryl lactate in a single stable non-aqueous single-phase biocompatible viscous vehicle, as recited in amended claim 10. Rather, Lyle discloses the use of polyvinylpyrrolidone and lauryl lactate in a cleansing composition (*See, Lyle*, Col. 4, lines 20-23, Col. 5, lines 37-38, and Col. 6, lines 42-54), and the use of glycerol monolaurate in a separate mascara formulation. (*See, Id.* at Col. 8, lines 6-8). Further, Lyle does not disclose a vehicle having a viscosity of between about 1,000 and 10,000,000 poise as recited in amended claim 10. Thus, claim 10 cannot be anticipated.

With regard to amended claim 11, it cannot be anticipated because Lyle does not disclose a stable non-aqueous, single-phase biocompatible viscous vehicle comprising a surfactant comprising polysorbate. In fact, Lyle does not disclose the use of polysorbate. Further, Lyle does not disclose a vehicle having a viscosity of between about 1,000 and 10,000,000 poise as recited in amended claim 11. Accordingly, claim 11 cannot be anticipated.

Turning to amended claim 15, it cannot be anticipated since Lyle does not disclose the use of polyvinylpyrrolidone, glycerol monolaurate or polysorbate, and lauryl lactate in a single stable non-aqueous single-phase biocompatible viscous vehicle, as recited in amended claim 15. In fact, Lyle does not disclose the use of polysorbate. Further, Lyle does not disclose the use of polyvinylpyrrolidone, glycerol monolaurate and lauryl lactate in a single stable non-aqueous

single-phase biocompatible viscous vehicle, as recited in amended claim 15. Rather, Lyle discloses the use of polyvinylpyrrolidone and lauryl lactate in two different elements, *i.e.*, in a cleansing composition (*See, Lyle*, Col. 4, lines 20-23, Col. 5, lines 37-38, and Col. 6, lines 42-54), and the use of glycerol monolaurate in a separate mascara formulation. (*See, Id.* at Col. 8, lines 6-8). Thus, amended claim 15 cannot be anticipated.

With regard to amended claim 16, it also cannot be anticipated since Lyle does not disclose a stable non-aqueous viscous protein formulation comprising at least one beneficial agent and polyvinylpyrrolidone, glycerol monolaurate or polysorbate, and lauryl lactate in a single, stable non-aqueous single-phase biocompatible viscous vehicle, as recited in amended claim 16. Lyle does not disclose the use of at least one beneficial agent, but rather discloses cosmetic active agents such as foundations, eyeshadows, blushers and mascara. (*See, Lyle*, Col. 1, lines 9-11). Further, as previously disclosed herein, Lyle does not disclose the use of polysorbate and also does not disclose the use of polyvinylpyrrolidone, glycerol monolaurate and lauryl lactate in a single stable non-aqueous single-phase biocompatible viscous vehicle as recited in amended claim 16. Rather, Lyle discloses the use of polyvinylpyrrolidone and lauryl lactate in a cleansing composition (*See, Lyle*, Col. 4, lines 20-23, Col. 5, lines 37-38, and Col. 6, lines 42-54), and the use of glycerol monolaurate in a separate mascara formulation. (*See, Id.* at Col. 8, lines 6-8). Accordingly, amended claim 16 cannot be anticipated.

Claims 46 and 47 are not anticipated, at the very least, as depending from novel independent claim 15 or 16, respectively.

Reconsideration and withdrawal of the anticipation rejections of claims 10, 11, 15, 16, 46 and 47 are requested.

Anticipation Rejection of Claims 10, 11, 15-18, 21-23, 27, 34, 35, 46 and 47 Under 35 U.S.C. § 102(e)

Claims 10, 11, 15-18, 21-23, 27, 34, 35, 46 and 47 stand rejected under 35 U.S.C. § 102(e) as assertedly being anticipated by Farinas et al. (U.S. Patent No. 5,928,666) (Office Action, at page 5). Applicants respectfully traverse this rejection, as hereinafter set forth.

Farinas et al. does not disclose each and every element of any of claims 10, 11, 15-18, 21-23, 27, 35, 46 and 47 as required for anticipation. For instance, Farinas et al. does not disclose a

stable non-aqueous single-phase biocompatible viscous vehicle comprising a polymer comprising polyvinylpyrrolidone, a surfactant comprising glycerol monolaurate, and a solvent comprising lauryl lactate, wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise, as recited in amended claim 10.

Farinas et al. discloses the use of glycerol monolaurate or lauryl lactate as a permeation enhancer, not the use of glycerol monolaurate as a surfactant and the use of lauryl lactate as a solvent in the stable non-aqueous single-phase biocompatible viscous vehicle, as recited in amended claim 10. (*See, Farinas et al.*, Col. 7, 13-30). Thus, Farinas et al. discloses that only one of glycerol monolaurate or lauryl lactate is used in the pharmaceutical formulation, but not both as required in amended claim 10. Further, Farinas et al. does not disclose a vehicle having a viscosity of between about 1,000 and 10,000,000 poise, as recited in amended claim 10. Thus, amended claim 10 cannot be anticipated.

With regard to amended claim 11, it cannot be anticipated since Farinas et al. does not disclose a stable non-aqueous single-phase biocompatible viscous vehicle comprising a surfactant comprising polysorbate. In fact, Farinas et al. does not disclose any use of polysorbate. Additionally, Farinas et al. does not disclose a vehicle having a viscosity of between about 1,000 and 10,000,000 poise, as recited in amended claim 11. Thus, amended claim 11 cannot be anticipated.

Amended claims 15 and 16 also cannot be anticipated since Farinas et al. does not disclose the use of glycerol monolaurate as a surfactant and the use of lauryl lactate as a solvent, as recited in amended claim 15 or 16. As previously established herein, Farinas et al. is limited to the use of glycerol monolaurate or lauryl lactate as a permeation enhancer, not the use of glycerol monolaurate as a surfactant and the use of lauryl lactate as a solvent, as recited in amended claims 15 and 16. (*See, Farinas et al.*, Col. 7, 13-30). Further, Farinas et al. does not disclose the use of polysorbate. Accordingly, amended claims 15 and 16 cannot be anticipated.

Amended claim 35 also cannot be anticipated since, as previously established herein, Farinas et al. does not disclose glycerol monolaurate as a surfactant and lauryl lactate as a solvent in the stable non-aqueous single-phase biocompatible viscous vehicle, as recited in amended claim 35. Also, Farinas et al. does not disclose the use of polysorbate. Thus, amended claim 35 is novel over Farinas et al.

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Dependent claims 17-18, 21-23, 27, 46 and 47 cannot be anticipated, at the very least, as depending from a novel independent claim.

Reconsideration and withdrawal of the anticipation rejections of claims 10, 11, 15-18, 21-23, 27, 35, 46 and 47 are requested.

CONCLUSION

In view of the foregoing amendments, and further in view of the arguments made, it is believed that this application is now in condition for allowance. Reconsideration and early notice of allowance is respectfully requested.

Respectfully submitted,



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